

Attorney Docket No.: **DEX-0255**  
Inventors: **Sun et al.**  
Serial No.: **10/016,634**  
Filing Date: **October 31, 2001**  
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**REMARKS**

Claims 1-17 are pending in the instant application. Claims 6 and 10-17 have been withdrawn from consideration and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5 and 7-9 have been rejected. Claim 1, 4 and 5 have been amended. Claims 2 and 3 have been canceled. New claims 18 through 27 have been added. Support for these amendments is provided in the specification at page 14, lines 9-16, page 14, line 17 through page 16, line 30, page 33, lines 14-20, page 34, lines 9-28, page 95 through page 101, Example 1 and claim 1. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Finality of Restriction Requirement**

The restriction requirement mailed August 11, 2003 has been made final. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 6 and 10-17. Applicants have also amended the claims to be drawn to the elected sequence SEQ ID NO:19 and its related sequence, SEQ ID NO:18. In light of the finality of this Restriction Requirement, Applicants reserve the

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right to file a divisional application to the canceled subject matter.

### **II. Claim to priority**

The Examiner suggests that the provisional application upon which priority is claimed fails to provide adequate support for the elected SEQ ID NO:19. Applicants respectfully direct the Examiner to Figure 14 setting forth SEQ ID NO:14 of U.S. provisional application Serial No. 60/244,758. This sequence is the complement or antisense to SEQ ID NO:18 which is related to SEQ ID NO:19. Accordingly, this provisional application provides adequate support for the instant claimed invention and recognition of the priority claim of October 31, 2000 is respectfully requested.

### **III. Objection to the Claims**

Claim 4-10 have been objected to as not reflecting the elected subject matter. The Examiner suggests that the claims should be amended to read on a polynucleotide SEQ ID NO:19 encoding polypeptide SEQ ID NO:115. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended independent claim 1 from which claims 4-10 depend to be drawn to a polynucleotide SEQ ID NO:18 or 19 or a polynucleotide

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encoding a polypeptide SEQ ID NO:115. As shown by the Sequence Listing filed with the instant application, SEQ ID NO:18 is related to SEQ ID NO:19 and therefore has been included in the pending claims. Withdrawal of this objection is respectfully requested in light of these claim amendments.

**IV. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. 112, first paragraph - Written Description**

Claims 1-5 and 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner has acknowledged SEQ ID NO:19 to meet the provision of written description but suggests that the claims encompass gene sequences, encoding sequence and so forth with other elements included in DNA, such as non-coding, regulatory regions, etc. for which there is no description. The Examiner also suggests that the specification does not provide adequate written description for polynucleotide having at least 75% sequence identity with SEQ ID NO:19. Claim 2 is also rejected as the Examiner suggests that the claimed SEQ ID NO:19 is genomic

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DNA revealed by screening genomic DNA database and that  
Applicants were not in possession of a cDNA.

Accordingly, in an earnest effort to advance the prosecution  
of this case, Applicants have canceled claim 2 and 3.

Applicants respectfully disagree with the Examiner's  
suggestion that Applicants have only shown possession of SEQ ID  
NO:19.

At the outset, it is respectfully pointed out that parts (c)  
and (d) have been amended and are now drawn to a nucleic acid  
sequence having 99% identity and hybridizing under stringent  
conditions and a nucleic acid sequence having 85% identity over  
its entire length, respectively. Support for these amendments  
are provided in the specification at page 14, line 15 through  
page 17, line 4, and page 33, lines 14 through 20. Applicants  
have also amended claim 1 to include part (e) drawn to a nucleic  
acid molecule which is an allelic variant of a nucleic acid of  
SEQ ID NO:19 encoding an amino acid sequence of SEQ ID NO:115 in  
accordance with teachings at page 34, lines 9-28 of the  
specification and to state that the nucleic acid molecule is  
differentially expressed in colon cancer tissues in accordance  
with teachings at page 116-120 of the instant specification.  
Detailed methodologies for ascertaining sequences which meet the

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structural and functional limitations of the instant amended claims are set forth in the specification at page 13, lines 9-28, and page 14, line 7 through page 17, line 4 and Example 1. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequences of SEQ ID NO:18 or 19 and their differential expression in colon cancer tissues, applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

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**v. Rejection of Claims 1 and 3-5 under 35 U.S.C. § 102(f) and 102(a)**

Claims 1 and 3-5 have been rejected under 35 U.S.C. § 102(f) and 102(a) as being anticipated by genomic database LIFESEQ Gold.

The Examiner suggests that since Applicants screened this proprietary database, Applicants did not themselves invent the claimed subject matter. Further the Examiner suggests that the sequence was available in the database prior to Applicants invention.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of the disclosure of the specification at page 116 lines 18-20 as an admission by Applicants that "in detecting overexpression of said polynucleotide applicants screened proprietary genomic database LIFESEQ Gold commercially available . . .". No where in Example 1 is this stated. Instead, what is taught in Example 1 beginning at page 116 of the instant specification are the steps utilized by Applicants, not Incyte Genomics Inc., to identify the colon cancer specific nucleic acid molecules of the present invention. As clearly stated in this Example, Applicants utilized their own

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set of algorithms referred to as CLASP™ to systematically interrogate and analyze gene expression data in the LIFESEQ Gold database. It is only by this systematic analysis wherein CLASP categorizes ESTs and genes by disease class and performs simultaneous parallel searching for ESTs and genes expressed selectively in defined tissue types and cancer disease states that the colon specific nucleic acid molecules of SEQ ID NO:18 and 19, encoding SEQ ID NO: 115 were identified.

But for applicants proprietary CLASP™ algorithms and the disclosure of the subject application, one of skill in the art would not know that the claimed colon cancer specific nucleic acids including SEQ ID NO:18 or 19 are colon specific or cancer specific, much less colon cancer specific.

In an earnest effort to clearly distinguish the present invention from expression data in the LIFESEQ Gold database, Applicants have amended claim to clarify that the isolated nucleic acid molecules are colon cancer specific. Support for this amendment is provided in Example 1 beginning at 116 wherein Applicants describe use of their CLASP™ algorithms to analyze and identify SEQ ID NO:18 and 19 as having CLASP5, meaning differential expression in cancer tissue, profiles.

While sequences or portions thereof may have been in the

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LIFESEQ database, the Examiner has not shown that the claimed colon cancer specific nucleic acids including SEQ ID NO:18 or 19 are disclosed. Accordingly, the LIFESEQ database cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(f) and 102(a) is therefore respectfully requested.

**VI. Rejection of Claims 1, 2, 4, 5 and 7-9 under 35 U.S.C. § 102(b)**

Claims 1, 2, 4, 5 and 7-9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by GenEMBL Accession Number AK 026675. The Examiner suggests that this reference describes a human cDNA which has 98% local similarity to instant SEQ ID NO:19. Further, the Examiner suggests that the referenced sequence has continuous stretches matching SEQ ID NO:19 and would be expected to hybridize to SEQ ID NO:19.

Accordingly, in an earnest effort to advance the prosecution of this case, as discussed in Section IV, *supra*, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence has 99% identity and hybridizes under stringent conditions. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 85% identity over its entire

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length. Applicants have also amended claim 1 to include part (e) drawn to a nucleic acid molecule which is an allelic variant of a nucleic acid of SEQ ID NO:18 or 19 encoding an amino acid sequence of SEQ ID NO:115 and to state that the nucleic acid molecule is differentially expressed in colon cancer.

GenEMBL Accession Number AK 026675 does not teach all the elements of the claims as amended and thus cannot anticipate the claimed invention. See MPEP § 2131.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

**VII. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. § 112, second paragraph**

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

In particular, the Examiner suggests that the recitation of "selectively hybridizes" is vague, indefinite and incomplete because the term is a relative one and no frame of reference is given.

Applicants respectfully disagree since what is meant by

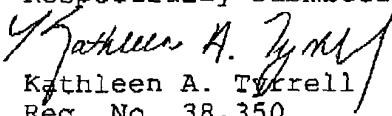
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"selectively hybridizes" is described in detail in the specification at page 14, lines 15-22. However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete this phrase and to clarify that the nucleic acid molecule shares 99% identity and hybridizes under stringent conditions. Detailed teachings of what is meant by stringent hybridization conditions is provided in the specification at page 14, line 23 through page 17, line 4.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is respectfully requested in light of this amendment.

#### **VIII. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,  
  
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